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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,472	11/21/2003	Yoshihiro Sokawa	55600-8013.US01	3649

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,472	SOKAWA ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/21/03 , ~~7/21/05~~*. 7/5/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to Applicants' petition filed June 2, 2004 to make the application special under the provisions of 37 CFR 1.102(d) and granted June 30, 2004. Claims 1-7 are pending and are the subject of this Office Action.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 11/21/2003 and 7/5/2005 have been considered by the examiner.

3. The Drawings filed on 11/21/2003 are accepted by the examiner.

Claim Objections

4. Claims 1 is objected to because of the following informalities: It is suggested that Applicants re write claim 1 by including the following phrase in line 2 between interferon tau therapy and selected, "wherein said conditions is".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5a. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting "an amount effective to produce an initial measurable increase in the subject's blood 2', 5'-OAS level, relative to the blood OAS". It is not clear to what degree of increase in synthetase levels would be needed to be

considered to measurable increase in 2', 5'-OAS levels. Claims 2-7 are rejected since they depend from claim 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6a. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being obvious over Soos et al. (U. S. Patent No. 6, 372, 206, reference 17 on the PTO1449 filed on 11/21/2003).

The instant invention describes interferon-tau pharmaceutical compositions useful for oral administration to treat autoimmune disorders (particularly multiple sclerosis), cell proliferative disorders (cancer) and viral disease (hepatitis C).

Soos et al. disclose the use of a therapeutically effective amount of orally administered ovine interferon-tau for treatment of viral disease, including hepatitis C, autoimmune disorder and cancer (col. 4, lines: 25-60). The reference also teaches an ovine interferon-tau (SEQ ID NO: 2) that is identical to SEQ ID NO: 2 of the instant invention. Soos et al. also disclose advantages of oral administration of interferon-tau (col. 9, lines: 5-24). Soos et al. disclose formulations of interferon-tau that are suitable for oral administration, including tablets, capsules, slow release preparations, and liquids (col. 15, lines: 3-40), as well as therapeutically effective dosages (up to $1x10^8$ units per day) that vary as necessary (col. 4, lines: 33-36 and col. 15, lines: 41-53). In fact, Soos et al. indicate that higher effective dosages of interferon-tau could be administered without the associated toxic side effects because of its low toxicity. The orally administered interferon-tau compositions of Soos et al. are deemed to be the same as, or only slightly different from those instantly claimed, because the instant claims do not distinguish over the prior art interferon-tau pharmaceutical composition. In addition, one of skilled in the art would readily adjust the administration to include the daily administration of interferon-tau and also for long term during the period of patient symptoms.

The reference also teaches the use of interferon-tau in treating immune system disorders such as EAE an animal model (column 13, lines 35-40), meeting the limitation of claim 4. Treatment of hepatitis C infection is also described by Soos et al (column 14, lines 16-22). Although, the reference does not teach the detection of hepatitis C infection by PCR amplification the HCV RNA, one skilled in the art would motivated to

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look at the presence HCV RNA PCR amplification with reasonable expectation of success because PCR amplification was well known tool at the time of the present invention for measuring the presence/levels of HCV RNA. This meets the limitation of claim 5. Soos et al. also discuss the use of interferon-tau oral administration for anti proliferative effect in treating cancer (column 14, lines 24-44). This meets a limitation of claim 6.

Although, Soos et al., has not discussed the changes in blood OAS level following the administration interferon tau, changes in blood OAS is inherent to the administration of interferon tau and thus would be expected to change with the administration of interferon-tau. Thus, OAS level would be anticipated to increase (when monitored) with the administration of interferon-tau meeting the limitation of claim 7. The person of ordinary skill in the art would have been motivated to modify the interferon dosage regiment of Soos et al. treat the instant conditions with a reasonable expectation of success. Therefore, the claims 1-7 are obvious over Soos et al. (U. S. Patent No. 6, 372, 206).

7. No claims are allowable over prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 11/05

ROBERT S. LANDSMAN
PRIMARY EXAMINER